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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,375	07/07/2000	ANTHONY DAVID ORMEROD	ABLE-0014	4066

7590

08/05/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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WASHINGTON, DC 20005-3315

EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/05/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/530,375

Applicant(s)

ORMEROD ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,25 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,25,28-32 and 36-39 is/are rejected.
- 7) ☒ Claim(s) 33-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 24, 25 and 28-39 are pending in this application.

Action Summary

1. The rejection of claim 29 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn as applicants have corrected claim dependency.
2. The rejection of claims 24, 25, 28 and 30-39 under 35 U.S.C. 103(a) over San-Doz Ltd. in view of Van Scott is hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 24, 25, 28, 29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Francoeur et al. (EP 0 435 436 A2).

Francoeur discloses a topical administration of a pharmaceutical agent, an aqueous solvent and a dermal penetration enhancer (page 2, lines 37-46). Page 2, lines 47-51 describe preferred dermal penetration enhancers, where the most preferred is oleic acid. Page 3, lines 43-44 teach the use of azithromycin as an active agent in the composition.

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4. Claims 24, 25, 28, 29, 32, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Pittrof et al. (US Pat. No. 5,376,646).

Pittrof teaches a topical preparation containing cholanolic acid and a lipid. The composition may also contain active substances of ingredients which such as immunosuppressives such as FK 506 and antibiotics (col. 1, lines 48-68). For the preparation of creams or salves paraffins, waxes, and fats can be incorporated (col. 2, lines 41-50). Adjuvants and additives may be incorporated such as penetration-enhancers i.e. oleic acid and also solvents may be incorporated i.e. ethanol, DMSO or organic amides (col. 2, lines 51-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 24, 25, 28-32 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pittrof et al. (US Pat. No. 5,376,646) in view of San-Doz Ltd. (WO 96/13249).

Pittrof teaches a topical preparation containing cholanolic acid and a lipid. The composition may also contain active substances of ingredients which such as immunosuppressives such as FK 506 and antibiotics (col. 1, lines 48-68). For the

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preparation of creams or salves paraffins, waxes, and fats can be incorporated (col. 2, lines 41-50). Adjuvants and additives may be incorporated such as penetration-enhancers i.e. oleic acid and also solvents may be incorporated i.e. ethanol, DMSO or organic amides (col. 2, lines 51-63). The prior art does not teach the topical used to treat the claimed dermatological conditions.

San-Doz Ltd. discloses a topical composition in the form of an emulsion that comprises the compound FK506. The composition is used to treat inflammatory and hyperproliferative skin diseases such as psoriasis, eczematous dermatitises, lupus erythematous, alopecia areata, etc. (page 12, lines 15-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of San-Doz to administer the composition of Pittrof to treat the claimed dermatological conditions. It is taught in San-Doz (page 12, lines 15-20) that FK 506 is used inflammatory and hyperproliferative skin diseases.

Response to Arguments

6. Applicant's arguments with respect to claims 24, 25 and 28-39 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

7. Claims 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Telephon Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Konata M. George
Patent Examiner
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